

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(FCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
 United States Patent and Trademark
 Office
 Box PCT
 Washington, D.C.20231
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

| | |
|---|---|
| Date of mailing (day/month/year) 12 May 2000 (12.05.00) | |
| International application No. PCT/US99/19537 | Applicant's or agent's file reference 031-PCT |
| International filing date (day/month/year) 27 August 1999 (27.08.99) | Priority date (day/month/year) 27 August 1998 (27.08.98) |
| Applicant ABOUL-HOSN, Walid, N. et al | |

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

29 February 2000 (29.02.00)

in a notice effecting later election filed with the International Bureau on:

2. The election was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

| | |
|---|-----------------------------------|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland | Authorized officer G. Bähr |
| Facsimile No.: (41-22) 740.14.35 | Telephone No.: (41-22) 338.83.38 |

Form PCT/I8/331 (July 1992)

US9919537

PC

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

Receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired) (12 characters maximum) 031-PCT
Box No. I TITLE OF INVENTION
INTRAVASCULAR CANNULATION APPARATUS AND METHODS OF USE
Box No. II APPLICANT

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

A-MED SYSTEMS INC.
2491 BOATMAN AVENUE
WEST SACRAMENTO, CALIFORNIA 95961
US

 This person is also inventor.Telephone No.
(916) 375 - 7400Facsimile No.
(916) 375 - 7444Teleprinter No.
NONEState (that is, country) of nationality:
USState (that is, country) of residence:
US

This person is applicant all designated States all designated States except the United States of America the United States of America only the States indicated in the Supplemental Box for the purposes of:

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

ABOUL-HOSN, WALID N.
3462 BRIDGEFORD DRIVE
SACRAMENTO, CALIFORNIA 95834
US

This person is:

 applicant only applicant and inventor inventor only (If this check-box is marked, do not fill in below.)State (that is, country) of nationality:
USState (that is, country) of residence:
US

This person is applicant all designated States all designated States except the United States of America the United States of America only the States indicated in the Supplemental Box for the purposes of:

 Further applicants and/or (further) inventors are indicated on a continuation sheet.**Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE**

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:

 agent common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

RYAN, DANIEL D.; KROMHOLZ, JOSEPH A.; MANION, JOHN M.; and MAKI,
ALLAN O.
633 WEST WISCONSIN AVENUE
MILWAUKEE, WISCONSIN 53203
US

Telephone No.
(414) 271 - 6555Facsimile No.
(14) 271 - 0198Teleprinter No.
NONE

Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANTS AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet is not to be included in the request.

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

KANZ, WILLIAM R.
4695 FRANCIS COURT
SACRAMENTO, CALIFORNIA 95822
US

This person is:

- applicant only
- applicant and inventor
- inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:
US

State (that is, country) of residence:
US

This person is applicant all designated all designated States except the United States of America of America only the States indicated in the Supplemental Box for the purposes of: States

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- applicant only
- applicant and inventor
- inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant all designated all designated States except the United States of America the United States of America only the States indicated in the Supplemental Box for the purposes of: States

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- applicant only
- applicant and inventor
- inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant all designated all designated States except the United States of America the United States of America only the States indicated in the Supplemental Box for the purposes of: States

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- applicant only
- applicant and inventor
- inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant all designated all designated States except the United States of America the United States of America only the States indicated in the Supplemental Box for the purposes of: States

Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

Regional Patent

- AP ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- EA Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- EP European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- OA OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Cote d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

National Patent (if other kind of protection or treatment desired, specify on dotted line):

- AL Albania
- AM Armenia
- AT Austria
- AU Australia
- AZ Azerbaijan
- BA Bosnia and Herzegovina
- BB Barbados
- BG Bulgaria
- BR Brazil
- BY Belarus
- CA Canada
- CH and LI Switzerland and Liechtenstein
- CN China
- CU Cuba
- CZ Czech Republic
- DE Germany
- DK Denmark
- EE Estonia
- ES Spain
- FI Finland
- GB United Kingdom
- GD Grenada
- GE Georgia
- GH Ghana
- GM Gambia
- HR Croatia
- HU Hungary
- ID Indonesia
- IL Israel
- IN India
- IS Iceland
- JP Japan
- KE Kenya
- KG Kyrgyzstan
- KP Democratic People's Republic of Korea
- KR Republic of Korea
- KZ Kazakhstan
- LC Saint Lucia
- LK Sri Lanka
- LR Liberia

- LS Lesotho
- LT Lithuania
- LU Luxembourg
- LV Latvia
- MD Republic of Moldova
- MG Madagascar
- MK The former Yugoslav Republic of Macedonia
- MN Mongolia
- MW Malawi
- MX Mexico
- NO Norway
- NZ New Zealand
- PL Poland
- PT Portugal
- RO Romania
- RU Russian Federation
- SD Sudan
- SE Sweden
- SG Singapore
- SI Slovenia
- SK Slovakia
- SL Sierra Leone
- TJ Tajikistan
- TM Turkmenistan
- TR Turkey
- TT Trinidad and Tobago
- UA Ukraine
- UG Uganda
- US United States of America
- UZ Uzbekistan
- VN Viet Nam
- YU Yugoslavia
- ZW Zimbabwe

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

-
-

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)

| Box No. VI PRIORITY CLAIMS | | <input type="checkbox"/> Further priority claims are indicated in the Supplemental Box. | | |
|---|----------------------------------|---|--|--|
| Filing date of earlier application (day/month/year) | Number of earlier application | Where earlier application is: | | |
| | | national application: country | regional application: regional Office | international application: receiving Office |
| item (1) 27/AUUST/1998 27/08/98 | 60/098,118 | US | | |
| item (2) | | | | |
| item (3) | | | | |

The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s): (1)
 * Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA)
 (if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):

ISA/ US

Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority):
 Date (day/month/year) Number Country (or regional Office)

Box No. VIII CHECK LIST: LANGUAGE OF FILING

This international application contains the following number of sheets:

| | | |
|---|---|----|
| request | : | 4 |
| description (excluding sequence listing part) | : | 37 |
| claims | : | 8 |
| abstract | : | 1 |
| drawings | : | 21 |
| sequence listing part of description | : | |
| Total number of sheets : | | 71 |

This international application is accompanied by the item(s) marked below:

1. fee calculation sheet
2. separate signed power of attorney
3. copy of general power of attorney; reference number, if any:
4. statement explaining lack of signature
5. priority document(s) identified in Box No. VI as item(s):
6. translation of international application into (language):
7. separate indications concerning deposited microorganism or other biological material
8. nucleotide and/or amino acid sequence listing in computer readable form
9. other (specify):

Figure of the drawings which should accompany the abstract:

Language of filing of the international application:

ENGLISH

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

BY
DANIEL B. RYAN, AGENT

8-27-99

For receiving Office use only

1. Date of actual receipt of the purported international application:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority (if two or more are competent): ISA/

6. Transmittal of search copy delayed until search fee is paid

2. Drawings:

- received:
 not received:

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

Form PCT/RO/101 (last sheet) (July 1998; reprint January 1999)

LegalStar 1999, Form PCTREQ

See Notes to the request form

This sheet is not part of and does not count as a sheet of the internal application.

PCT
FEE CALCULATION SHEET
Annex to the Request

For receiving Office use only

International application No.

Applicant's or agent's
file reference

031-PCT

Date stamp of the receiving Office

Applicant
A-MED SYSTEMS, INC.

CALCULATION OF PRESCRIBED FEES

1. TRANSMITTAL FEE

240.00 T

2. SEARCH FEE

450.00 S

International search to be carried out by **USPTO**
(If two or more International Searching Authorities are competent in relation to the international application, indicate the name of the Authority which is chosen to carry out the international search.)

3. INTERNATIONAL FEE

Basic Fee

The international application contains **71** sheets.

first 30 sheets

455.00 b₁

41 x **\$10.00** = **410.00** b₂
remaining sheets additional amount

410.00 b₂

Add amounts entered at b₁ and b₂ and enter total at B

865.00 B

Designation Fees

The international application contains **+10** designations.
10 x **105.00** = **1,050.00** D

number of designation fees amount of designation fee
payable (maximum 10)

1,050.00 D

Add amounts entered at B and D and enter total at I

1,915.00 I

(Applicants from certain States are entitled to a reduction of 75% of the international fee. Where the applicant is (or all applicants are) so entitled, the total to be entered at I is 25% of the sum of the amounts entered at B and D.)

15.00 P

4. FEE FOR PRIORITY DOCUMENT (if applicable)

5. TOTAL FEES PAYABLE

Add amounts entered at T, S, I and P, and enter total in the TOTAL box

2,620.00

TOTAL

The designation fees are not paid at this time.

MODE OF PAYMENT

authorization to charge
deposit account (see below)
 cheque
 postal money order

bank draft
 cash
 revenue stamps

coupons
 other (specify):

DEPOSIT ACCOUNT AUTHORIZATION (this mode of payment may not be available at all receiving Offices)

The RO/ **US** is hereby authorized to charge the total fees indicated above to my deposit account.

(this check-box may be marked only if the conditions for deposit accounts of the receiving Office so permit) i
hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my
deposit account.

is hereby authorized to charge the fee for preparation and transmittal of the priority document to the Internation:
Bureau of WIPO to my deposit account.

06-2360

27 AUGUST 1999

Deposit Account Number

Date (day/month/year)

Signature

'The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority must be indicated by the applicant on the line below.'

IPEA/ US

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:
The undersigned requests that the international application specified below be the subject of
international preliminary examination according to the Patent Cooperation Treaty and
hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only

Identification of IPEA

Date of receipt of DEMAND

| Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION | | Applicant's or agent's file reference |
|---|---|--|
| International application No. PCT/US99/19537 | International filing date (day/month/year) 27/AUGUST/1999 (27/08/99) | (Earliest) Priority date (day/month/year) 27/AUGUST/1998 (27/08/98) |

Title of invention
INTRAVASCULAR CANNULATION APPARATUS AND METHODS OF USE

Box No. II APPLICANT(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

A-MED SYSTEMS, INC.
2491 BOATMAN AVENUE
WEST SACRAMENTO, CALIFORNIA 94961
US

Telephone No.:
(916) 375 - 7400

Faxsimile No.:
(916) 375 - 7444

Teleprinter No.:
NONE

State (that is, country) of nationality:
US

State (that is, country) of residence:
US

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

ABOUL-HOSN, WALID N.
4625 CHICAGO AVENUE
FAIR OAKS, CALIFORNIA 95628 US

State (that is, country) of nationality:
US

State (that is, country) of residence:
US

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

KANZ, WILLIAM R.
4695 FRANCIS COURT
SACRAMENTO, CALIFORNIA 94822 US

State (that is, country) of nationality:
US

State (that is, country) of residence:
US

Further applicants are indicated on a continuation sheet.

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The following person is agent common representative

- and has been appointed earlier and represents the applicant(s) also for international preliminary examination.
 is hereby appointed and any earlier appointment of (an) agent(s) /common representative is hereby revoked.
 is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: (Family name followed by given name; for a legal entity, full official designation)
The address must include postal code and name of country.

RYAN, DANIEL D.; KROMHOLZ, JOSEPH A.; MANION, JOHN M.; MAKI,
 ALLAN O.
 P.O. BOX 26618
 MILWAUKEE, WISCONSIN 53226
 US

Telephone No.:
 (262) 797 - 6700

Facsimile No.:
 (262) 797 - 9600

Teleprinter No.:
 NONE

Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION**Statement concerning amendments:***

1. The applicant wishes the international preliminary examination to start on the basis of:

- the international application as originally filed
 the description as originally filed
 as amended under Article 34
 the claims as originally filed
 as amended under Article 19 (together with any accompanying statement)
 as amended under Article 34
 the drawings as originally filed
 as amended under Article 34

2. The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.

3. The applicant wishes the start of the international preliminary examination to be postponed until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). (This check-box may be marked only where the time limit under Article 19 has not yet expired.)

- * Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: **ENGLISH**

- which is the language in which the international application was filed.
 which is the language of a translation furnished for the purposes of international search.
 which is the language of publication of the international application.
 which is the language of the translation (to be) furnished for the purposes of international preliminary examination.

Box No. V ELECTION OF STATES

The applicant hereby elects all eligible States (*that is, all States which have been designated and which are bound by Chapter II of the PCT*)

excluding the following States which the applicant wishes not to elect:

Box No. VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

- | | | |
|--|---|--------|
| 1. translation of international application | : | sheets |
| 2. amendments under Article 34 | : | sheets |
| 3. copy (or, where required, translation) of amendments under Article 19 | : | sheets |
| 4. copy (or, where required, translation) of statement under Article 19 | : | sheets |
| 5. letter | : | sheets |
| 6. other (specify) | : | sheets |

For International Preliminary Examining Authority use only
received not received

| | |
|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> |

The demand is also accompanied by the item(s) marked below:

- | | |
|--|---|
| 1. <input checked="" type="checkbox"/> fee calculation sheet | 4. <input type="checkbox"/> statement explaining lack of signature |
| 2. <input type="checkbox"/> separate signed power of attorney | 5. <input type="checkbox"/> nucleotide and or amino acid sequence listing in computer readable form |
| 3. <input type="checkbox"/> copy of general power of attorney; reference number, if any: | 6. <input checked="" type="checkbox"/> other (specify): NOTIFICATION OF CHANGE |

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).

By _____

Daniel D. Ryan, Agent

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:

2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):

3. The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply. The applicant has been informed accordingly.
4. The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.
5. Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

For International Bureau use only

Demand received from IPEA on:

PCT

FEE CALCULATION SHEET

Annex to the Demand for international preliminary examination

| | | |
|--|---|--|
| International application No. | PCT/US99/19537 | For International Preliminary Examining Authority use only |
| Applicant's or agent's file reference | 16626-PCT | Date stamp of the IPEA |
| Applicant A-MED SYSTEMS, INC. et al. | | |
| Calculation of prescribed fees | | |
| 1. Preliminary examination fee | 490.00 | P |
| 2. Handling fee (Applicants from certain States are entitled to a reduction of 75% of the handling fee. Where the applicant is (or all applicants are) so entitled, the amount to be entered at H is 25% of the handling fee.) | 153.00 | H |
| 3. Total of prescribed fees Add the amounts entered at P and H and enter total in the TOTAL box | 643.00 TOTAL | |
| Mode of Payment | | |
| <input type="checkbox"/> authorization to charge deposit account with the IPEA (see below) | <input type="checkbox"/> cash | |
| <input checked="" type="checkbox"/> cheque | <input type="checkbox"/> revenue stamps | |
| <input type="checkbox"/> postal money order | <input type="checkbox"/> coupons | |
| <input type="checkbox"/> bank draft | <input type="checkbox"/> other (specify): _____ | |

Deposit Account Authorization (this mode of payment may not be available at all IPEAs)

The IPEA/ US is hereby authorized to charge the total fees indicated above to my deposit account.

(this check-box may be marked only if the conditions for deposit accounts of the IPEA so permit) is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.

06-2360

29 February 2000

Deposit Account Number

Date (day/month/year)

Signature

Form PCT/IPEA/401 (Annex) (July 1998; reprint January 2000)

LegalStar 2000, Form PCTDFEE

See Notes to the fee calculation sheet

PATENT COOPERATION TREATY

PCT

REC'D 11 AUG 2000

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

PCT

(PCT Article 36 and Rule 70)

| | | |
|--|--|--|
| Applicant's or agent's file reference 031-PCT | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US99/19537 | International filing date (day/month/year) 27 AUGUST 1999 | Priority date (day/month/year) 27 AUGUST 1998 |
| International Patent Classification (IPC) or national classification and IPC IPC(7): A61M 3/00 and US CL.: 604/43 | | |
| Applicant A-MED SYSTEMS INC. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

| | |
|--|---|
| Date of submission of the demand 29 FEBRUARY 2000 | Date of completion of this report 05 MAY 2000 |
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 | Authorized officer  <i>For</i> DEBORAH BLYVEIS |
| Facsimile No. (703) 305-3230 | Telephone No. (703) 308-2110 |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/19537

I. Basis of the report

1. With regard to the elements of the international application:*

 the international application as originally filed the description:

pages 1-37, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

 the claims:

pages 38-45, as originally filed

pages NONE, as amended (together with any statement) under Article 19

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

 the drawings:

pages 1-21, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

 the sequence listing part of the description:

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 contained in the international application in printed form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. The amendments have resulted in the cancellation of: the description, pages NONE the claims, Nos. NONE the drawings, sheets/fig. NONE5. This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/19537

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>1-38</u> | YES |
| | Claims <u>NONE</u> | NO |
| Inventive Step (IS) | Claims <u>1-38</u> | YES |
| | Claims <u>NONE</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-38</u> | YES |
| | Claims <u>NONE</u> | NO |

2. citations and explanations (Rule 70.7)

Claims 1-38 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the slidably coupled flow paths.

----- NEW CITATIONS -----

NONE

PATENT COOPERATION TREATY

RECEIVED
AUG 11 2001From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: DANIEL D RYAN
 RYAN, KROMHOLZ, & MANION, S.C.
 POST OFFICE BOX 26618
 MILWAUKEE, WISCONSIN 53226

PCT
 RYAN KROMHOLZ & MANION S.C.
 NOTIFICATION OF TRANSMITTAL OF
 INTERNATIONAL PRELIMINARY
 EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing (day/month/year) 08 AUG 2000

| | | | |
|--|--|--|--|
| Applicant's or agent's file reference 031-PCT | | IMPORTANT NOTIFICATION | |
| International application No. PCT/US99/19537 | International filing date (day/month/year) 27 AUGUST 1999 | Priority Date (day/month/year) 27 AUGUST 1998 | |
| Applicant A-MED SYSTEMS INC. | | | |

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

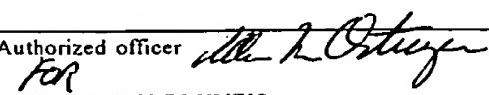
For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

| | |
|--|---|
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230 | Authorized officer <i>DEBORAH BLYVEIS</i> DEBORAH BLYVEIS Telephone No. (703) 308-2110 |
|--|---|

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

| | | |
|--|---|--|
| Applicant's or agent's file reference 031-PCT | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US99/19537 | International filing date (day/month/year) 27 AUGUST 1999 | Priority date (day/month/year) 27 AUGUST 1998 |
| International Patent Classification (IPC) or national classification and IPC IPC(7): A61M 3/00 and US CL.: 604/43 | | |
| Applicant A-MED SYSTEMS INC. | | |

| |
|--|
| <ol style="list-style-type: none"> 1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of <u>3</u> sheets. <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p> |
| <ol style="list-style-type: none"> 3. This report contains indications relating to the following items: <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step or industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application |

| | |
|--|---|
| Date of submission of the demand 29 FEBRUARY 2000 | Date of completion of this report 05 MAY 2000 |
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 | Authorized officer  For DEBORAH BLYVEIS |
| Facsimile No. (703) 305-3230 | Telephone No. (703) 308-2110 |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/19537

I. Basis of the report

1. With regard to the elements of the international application:*

 the international application as originally filed the description:

pages 1-37

pages NONE

pages NONE

, filed with the letter of _____

 the claims:

pages 38-45

pages NONE

pages NONE

pages NONE

, filed with the letter of _____

 the drawings:

pages 1-21

pages NONE

pages NONE

, filed with the letter of _____

 the sequence listing part of the description:

pages NONE

pages NONE

pages NONE

, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 contained in the international application in printed form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. The amendments have resulted in the cancellation of: the description, pages NONE the claims, Nos. NONE the drawings, sheets/fig. NONE5. This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/19537

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>1-38</u> | YES |
| | Claims <u>NONE</u> | NO |
| Inventive Step (IS) | Claims <u>1-38</u> | YES |
| | Claims <u>NONE</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-38</u> | YES |
| | Claims <u>NONE</u> | NO |

2. citations and explanations (Rule 70.7)

Claims 1-38 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the slidably coupled flow paths.

----- NEW CITATIONS -----

NONE

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: DANIEL D RYAN
633 WEST WISCONSIN AVENUE
MILWAUKEE, WISCONSIN 53203

DRC

APR 0

RYAN KROMHOLZ & PARTNERS

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT
OR THE DECLARATION

(PCT Rule 44.1)

30 MAR 2000

| | |
|--|---|
| Applicant's or agent's file reference 031-PCT 16626-PCT | FOR FURTHER ACTION See paragraphs 1 and 4 below |
| International application No. PCT/US99/19537 | International filing date (day/month/year) 27 AUGUST 1999 |
| Applicant A-MED SYSTEMS INC. | |

1. The applicant is hereby notified that the international search report has been established and is transmitted herewith.
- Filing of amendments and statement under Article 19:**
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):
- When?** The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.
- Where?** Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35
- For more detailed instructions, see the notes on the accompanying sheet.
2. The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.
3. With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.
4. **Further action(s):** The applicant is reminded of the following:
- Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 bis 1 and 90 bis 3, respectively, before the completion of the technical preparations for international publication.
- Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).
- Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

| | |
|---|---------------------------------------|
| Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 | Authorized officer DEBORAH BLYVEIS |
| Facsimile No. (703) 305-3230 | Telephone No. (703) 308-2110 |

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | | |
|--|--|--|
| Applicant's or agent's file reference 031-PCT | FOR FURTHER ACTION | see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. |
| International application No. PCT/US99/19537 | International filing date (day/month/year) 27 AUGUST 1999 | (Earliest) Priority Date (day/month/year) 27 AUGUST 1998 |
| Applicant A-MED SYSTEMS INC. | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Certain claims were found unsearchable (See Box I).
2. Unity of invention is lacking (See Box II).
3. The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing
 - filed with the international application.
 - furnished by the applicant separately from the international application,
 - but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
 - transcribed by this Authority.
4. With regard to the title, the text is approved as submitted by the applicant.
 - the text has been established by this Authority to read as follows:
5. With regard to the abstract,
 - the text is approved as submitted by the applicant.
 - the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is:
Figure No. 17
 - as suggested by the applicant.
 - because the applicant failed to suggest a figure.
 - because this figure better characterizes the invention.

None of the figures.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The technical features mentioned in the Abstract do not include a reference sign between parentheses (PCT Rule 8.1(d)).

NEW ABSTRACT

This invention is a cannulation apparatus, and related methods for providing indirect access to a surgical site within a patient. The cannulation apparatus includes at least two fluid flow paths that are slidable coupled (40)(50) to one another, and selectively positional within the patient. The first, the second flow paths may be advanced through a single incision disposed remotely from the surgical field to first, and second predetermined locations within the patient. Exemplary sites for the incision include the groin region or in the neck region of the patient. The cannulation apparatus, and method of the present invention are particularly suited for use in providing cardiopulmonary support during cardiac surgery, including coronary artery bypass graft surgery. The cannulation apparatus of the present invention also provides an entry site for one or more support devices used in the surgical procedure.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/19537**A. CLASSIFICATION OF SUBJECT MATTER**IPC(7) :A61M 3/00
US CL :604/43

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/16-18; 604/4, 43, 96-102; 606/192, 194

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| A,P | US 5,814,016 A (VALLEY et al.) 29 September 1998, Abstract. | 1-38 |

Further documents are listed in the continuation of Box C.

See patent family annex.

| | | |
|---|-----|--|
| Special categories of cited documents: | "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" document defining the general state of the art which is not considered to be of particular relevance | "X" | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "E" earlier document published on or after the international filing date | "Y" | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&" | document member of the same patent family |
| "O" document referring to an oral disclosure, use, exhibition or other means | | |
| "P" document published prior to the international filing date but later than the priority date claimed | | |

Date of the actual completion of the international search

13 MARCH 2000

Date of mailing of the international search report

30 MAR 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

DEBORAH BLYVEIS

Telephone No. (703) 308-2110

INTERNATIONAL SEARCH REPORT

International application No.

PCT US99 13666

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) A61M 5/00; 25/00

US CL 604/158, 264, 523

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/104-109, 158, 159, 164, 170, 171, 173, 264, 523, 524, 528, 532-537; 606 108

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (Name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------------------|
| Y | US 4,362,163 A (KRICK) 07 December 1982, entire document. | 28, 29 |
| Y | US 4,682,978 A (MARTIN) 28 July 1987, entire document. | 7 |
| X | US 5,630,823 A (SCHMITZ-RODE et al.) 20 May 1997, entire document. | 22-27 |
| --- | | ----- |
| Y | | 13, 15, 21, 28, 29 |
| Y,P | US 5,771,888 A (KEIM) 30 June 1998, entire document. | 1, 2, 4, 6, 9, 10, 12, 14, 15, 21 |

Further documents are listed in the continuation of Box C.



See patent family annex.

| | | | |
|-----|--|-----|--|
| *A* | Special categories of cited documents | *T* | later document published after the international filing date or priority date that is essential to the application but cited to understand the principle or theory underlying the invention |
| *E* | document defining the general state of the art which is not considered to be of particular relevance | *X* | document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| *L* | earlier document published on or after the international filing date | | document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| *M* | document which may throw doubt on priority claims, or which is cited to establish the publication date of another citation or other special reasons as specified | | document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| *P* | document referring to an oral disclosure, use, exhibition or other means | | document member of the same patent family |
| | document published prior to the international filing date but later than the priority date claimed | | |

Date of the actual completion of the international search

12 AUGUST 1999

Date of mailing of the international search report

31 AUG 1999

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US99/13666

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|--------------------------------------|
| Y,P | US 5,817,057 A (BERENSTEIN et al.) 06 October 1998, entire document. | 1, 2, 4, 6, 9, 10, 12, 14, 15, 21 |
| A | US 4,508,535 A (JOH et al.) 02 April 1985, Figs. 5 and 8, col. 9 lines 35-51, and col. 10 lines 22-50. | 22-30 |